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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,526	02/26/2004	Kenneth W. Dobie	BIOL0002US	9932

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EXAMINER	
EPPS FORD, JANET L	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,526	DOBIE ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13,20-23 and 46-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-13,20-23 and 46-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/29/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-23, and 31, in the reply filed on 3-28-06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 2, 14-19 and 24-45 have been canceled in the response filed 3-28-06.

3. Claims 1, 3-13, 20-23, and new claims 46-49 are pending for examination.

Specification

4. The specification as filed discloses multiple sequences of 10 nucleobases or greater on page 62, however there are no sequence identifiers (SEQ ID NO:) associated with these sequences. According to 37 CFR 1.821 through 1.825, Applicants are required to assign a sequence identifier (SEQ ID NO) for every disclosed un-branched nucleic acid sequence of 10 or more nucleotides and list these sequences individually in a Sequence Listing as a separate part of the disclosure.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4-6, 10-13, and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (US Patent No. 5,861,244.)

7. Wang et al. describes SEQ ID NO: 354 (see col. 25-26), which is a single stranded nucleic acid molecule of 12 nucleobases in length that comprises an 8 nucleobase portion of SEQ ID NO: 19 of the instant application, see the following underlined sequence. SEQ ID NO: 354 of Wang et al. has the following sequence: 5'-**TTCTTTCC**CCTC-3'. The underlined sequence corresponds to nucleobases 9 through 16 of SEQ ID NO: 19 of the instant application.

The instant prior art is applied to claims 10-13 since the claims do not recite wherein the recited complementarity, specifically 70%, 80%, 90%, and 95%, is over the entire length of the claimed compound. Wang et al. teach an 8-nucleobase portion that has 100% complementarity to a sequence of nucleobases 332-351 (the region corresponding to SEQ ID NO: 161) of SEQ ID NO: 4 of the instant specification.

8. Claims 1 and 3-6, 10-13, and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Francisco et al. (GenBank Accession No. L78573.1; November 29, 1996).

Francisco et al. discloses an oligonucleotide of 21 base pairs in length comprising an 11 base pair contiguous stretch of nucleobases that are 100% identical to nucleobases 9 through 19 of SEQ ID NO: 19 of the instant application. The oligonucleotide of Francisco et al. comprises an 11 nucleobase portion that has 100% complementarity to a sequence of nucleobases 332-351 of SEQ ID NO: 4 of the instant specification.

9. Claims 1, 3-8, 10-13, 20-23, and 46-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al. (US Patent No. 6,228,642).

Baker et al. disclose a chimeric oligonucleotide of 20 nucleobases in length comprising a 8-nucleobase sequence that is 100% identical to a sequence of SEQ ID NO: 19 of the instant invention, and further comprises 100% complementarity to an 8-nucleobase portion of a sequence of nucleobases 332-351 (the region corresponding to SEQ ID NO: 161) of SEQ ID NO: 4 of the instant specification.

Specifically, SEQ ID NO: 16 and 293 of Baker et al. (see Table 31, col. 61-62, SEQ ID NO: 293) comprises 2'-MOE wings and a deoxy gap region of ten 2'-deoxynucleotides. The internucleoside linkages of the oligonucleotide are phosphorothioate, and throughout the oligonucleotide all cytidine residues are 5-methylcytidines. Additionally, Baker et al. teaches a variety of agents that enhance the uptake and penetration of oligonucleotides administered to cells (see col. 13, line 5 through col. 14). Moreover, Baker et al. teaches that the term "oligonucleotide" (within the context of their invention) refers to an oligomer or polymer of ribonucleic acid or deoxyribonucleic acid (col. 6, lines 55-65).

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claim 1, 3-6, 8, 10-13, 20-23, and 46-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Dobie et al. (US Patent Application 2003-232438).

13. Dobie et al. disclose a chimeric oligonucleotide comprising a 10-nucleobase sequence that is 100% identical to a sequence of SEQ ID NO: 19 of the instant invention, and further comprises 100% complementarity to a 10-nucleobase portion of a sequence of nucleobases 332-351 (the region corresponding to SEQ ID NO: 161) of SEQ ID NO: 4 of the instant specification. Specifically, SEQ ID NO: 41 of Dobie et al. (see Table 1, page 30), comprises 2'-MOE wings and a deoxy gap region of ten 2'-deoxynucleotides. The internucleoside linkages of the oligonucleotide are phosphorothioate, and throughout the oligonucleotide all cytidine residues are 5-methylcytidines. Additionally, Dobie et al. teaches a variety of agents that enhance the uptake and penetration of oligonucleotides administered to cells (see page 16, paragraphs [0124]-[125]).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1, 3-13, 20-23 and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. as applied to claims 1, 3-8, 10-13, 20-23, and 46-47 set forth above, in view of Hammond et al. and Elbashir et al.

However, Baker et al. do not teach wherein their disclosed oligonucleotides are short interfering RNA (siRNA) molecules.

Hammond et al. teach that antisense and RNA interference are two methods of silencing expression of a gene and that RNA interference possesses characteristics that make it superior to antisense. For example, on page 110, first column, Hammond teaches that antisense methods are straightforward but suffer from "questionable specificity and incomplete efficacy." RNA interference on the other hand, "has been shown in diverse organisms to inhibit gene expression in a sequence-specific manner" (same page and column) and requires only a few molecules of dsRNA per cell to silence expression.

Elbashir et al. teach that synthetic RNA molecules that are 21-22 nucleotides in length mediate RNA interference efficiently. Elbashir et al. named these short duplexes "short interfering RNAs" (siRNAs). Elbashir et al. also teach that 21-23 nucleotide RNAs are implicated as the guide RNAS for target recognition in RNA interference. Furthermore, Elbashir et al. teach that 21-nucleotide complexes provide a new tool for studying gene function in mammalian cells and can be used in a gene-specific manner (see page 497, concluding paragraph).

It would have been obvious to the ordinary skilled artisan, at the time of the instant invention, to modify the teachings of an antisense oligonucleotide compound of Baker et al. with the teachings of Elbashir et al. in the design of the presently claimed invention. One of ordinary skill in the art would have been motivated to make this modification since Hammond et al. teach that siRNA molecules are superior to antisense molecules since RNA interference requires only a few molecules of dsRNA per cell to silence expression, function in a sequence specific manner, and do not suffer from questionable specificity and incomplete efficacy.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Janet L. Epps-Ford, Ph.D.
Primary Examiner
Art Unit 1633

JLE